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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,766	06/28/2000	George W. Hawkins	99,215-A	5882

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AMERSHAM BIOSCIENCES  
PATENT DEPARTMENT  
800 CENTENNIAL AVENUE  
PISCATAWAY, NJ 08855

EXAMINER
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CALAMITA, HEATHER

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/605,766	HAWKINS, GEORGE W.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,36,38-60 and 64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,36,38-60 and 64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of Application, Amendments, and/or Claims*

1. Currently, claims 1, 36, 38-60 and 64 are pending. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. Any objections and rejections not reiterated below are hereby withdrawn.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 36,37,40,45,47,49 & 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Cottingham et al. (WO 97/10056, 03/20/1997).

Cottingham et al. teach an apparatus for performing biological reactions (see whole doc. esp. abstract & figure 4, DNA amplification and probe assay device) comprising a substrate (see page 13 line 3-4 DNA card with bottom and top layer) and an array with biomolecular probes positioned on first surface (see page 10 lines 1-15 teaching an array arrangement of DNA amplification and assay reagents which includes primers and probes spotted on surface) and flexible layer affixed to first surface by an adhesive layer forming reaction volume (see page 13 lines 9 & 10 adhesive binding a plastic film) and port (see page 13 line 21 & last line air vent and sample port). The ports extend through flexible layer (see Figure 4 detail 28 & 26). The apparatus taught by Cottingham et al. is inherently watertight, as a port is described for entry of the sample. Cottingham et al. also do not describe sample leakage indicating the sample chamber is watertight (see p.

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5 second paragraph). They teach apparatus may further comprise measuring instrument and heated carrier (see figure 13 detail 80, 81 and page 21 first full paragraph).

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43 & 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al. (WO 97/10056, 03/20/1997) in view of Rehman et al. (Nucleic Acids Research, January 1999).

The teachings of Cottingham et al. are described previously.

Cottingham et al. do not teach polyacrylamide.

Rehman et al. teach polyacrylamide layer for binding probes (see p. 649, Introduction paragraph 2).

One of ordinary skill in the art would have been motivated to apply polyacrylamide as taught by Rehman et al. (Nucleic Acids Research, January 1999) polyacrylamide to the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order to immobilize DNA probes at a greater capacity. Rehman et al. (Nucleic Acids Research, January 1999) state that polyacrylamide provides for great probe capacity, density, lower non-specific binding levels and relatively high thermal stability particularly in amplifications of solid phase PCR and hybridization assays (see p. 649, paragraph 2). It would have been prima facie obvious to apply the polyacrylamide as taught by Rehman et al. (Nucleic Acids Research,

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January 1999) to the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) for DNA probe assays in order to increase the hybridization efficiency of the probe reagents.

5. Claims 48,50-56 & 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al. (WO 97/10056, 03/20/1997) in view of Bjornson et al. (WO 99/19717, 04/22/1999)

The teachings of Cottingham et al. are described previously.

Cottingham do not teach flexible layer with polyester, polypropylene.

Bjornson et al. teach a variety of well known flexible films such as plastics acrylics and polyethylenes of varying widths (see p. 17 line 15-17). Bjornson et al. teach rolling with roller (see figure 5). Bjornson et al. teach adhesives (see page 25 line 9).

One of ordinary skill in the art would have been motivated to apply rollers and flexible films as taught by Bjornson et al. (WO 99/19717, 04/22/1999) to the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order to construct a cover for the reaction and press to ensure a seal of the film. It would have been prima facie obvious to apply rollers and flexible films as taught by Bjornson et al. (WO 99/19717, 04/22/1999) to the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order to ensure a sealed layer in Cottingham's device.

6. Claims 39, 41, 42, 46, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al. (WO 97/10056, 03/20/1997) in view of Besemer et al. (USPN 5,945,334, 08/31/1999).

The teachings of Cottingham et al. are described previously.

Cottingham et al. do not teach sample chip and heater

Besemer et al. teach a chip device containing a substrate having an array of probes

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attached to cavity (see col. 1 line 65- col. 2 line 3 & claims 1 & 2). The body includes two inlets that allow fluids into and through cavity. A seal, plug or any other seal may be provided for each inlet to retain fluid within cavity (see col. 6 line 39). The body is formed by welding two pieces together. Besemer et al. also teach heaters may be connected to device (col. 9 line 62). Besemer et al. also teach of variety of surface supports including glass, silicon, Ge, GaAS (see col. 4 line 60-64).

One of ordinary skill in the art would have been motivated to use chips as taught by Besemer et al. (USPN 5,945,334, 08/31/1999) with the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order perform hybridization assays. Array chips were well known and commonly practiced in the art to perform detection assays. It would have been prima facie obvious to use chips as taught by Besemer et al. (USPN 5,945,334, 08/31/1999) with the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order to perform a plurality of different assays simultaneously.

7. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al. (WO 97/10056, 03/20/1997) in view of Besemer et al. (USPN 5,945,334, 08/31/1999) in further view of Van Antwerp et al. (USPN 5,786,439, 07/28/1998).

The teachings of Cottingham et al. and Besemer et al. are described previously.

Cottingham et al. do not teach the claimed layer of water-soluble compound.

Van Antwerp et al. teach coating the surface of biosensor with uniform hydrogel (see abstract). The hydrogel may be PEG 600 (see claim 10).

One of ordinary skill in the art would have been motivated to apply PEG-600 coatings as taught by Van Antwerp et al. (USPN 5,786,439, 07/28/1998) to the chip array device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) and Besemer et al. in order to protect the array from interfering chemicals. Antwerp et al state that the hydrogel layer protects from interfering chemicals such as electrolytes and proteins but allows water to pass through to allow the arrays to accurately measure

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analyte (see column 1 lines 46-50). It would have been prima facie obvious to apply hydrogel as taught by Van Antwerp et al. (USPN 5,786,439, 07/28/1998) to the chip array device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) and Besemer et al. in order to allow the array to accurately measure analytes without interference from other chemicals.

### *Response to Arguments*

8. Applicant's arguments filed March 14, 2005, have been fully considered but they are not persuasive. With respect to the 102 (b) rejections Applicant's assert the invention disclosed by Cottingham et al. is comprised of three separate plastic layers which are held together by pressure sensitive adhesives between each layer and this is not disclosed in the instant invention. The claim uses the open language of comprising and therefore it is irrelevant that Cottingham teach 3 layers.

Additionally applicant argues that Cottingham do not teach an array of biomolecular probes positioned in the first surface of the substrate. Cottingham teach on p. 9 lines 7-8 and p 10 lines 1-2 a rectangular array of discrete sample cells which contain a dried DNA amplification reagent (nucleic acid primers, and a polymerase).

Applicant further argues Cottingham do not teach the chambers are watertight. The Examiner asserted in the previous office action that this feature was inherent as Cottingham discloses a sealed sample chamber. A sealed sample chamber is inherently watertight as the sample does not leak from the chamber.

With respect to the 103 (a) rejections, Applicant argues, in all of the 103(a) rejections, the Examiner's conclusion of obviousness is based upon the improper application of Cottingham's teachings. Applicant's arguments with respect to these rejections have been considered but are moot in view of the clarification of the applicability of Cottingham's teachings. For all of the aforementioned reasons, the Examiner is not persuaded to withdraw the rejections against claims 1, 36, 38-60 and 64.

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*Conclusion*

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

*Correspondence*

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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hgc

  
JEFFREY FREDMAN  
PRIMARY EXAMINER

5/13/05